510(k) Summary

Cayenne Medical, Inc.

AperFix Femoral Implant with Inserter

ADMINISTRATIVE INFORMATION

Manufacturer Name:	Cayenne Medical, Inc. 16597 N. 92nd St., Suite 101 Scottsdale, AZ 85260 Telephone (480) 520-3661 FAX (480) 520-3670
Official Contact:	Kereshmeh Shahriari

DEVICE NAME

Classification Names:	Screw, fixation, bone
Trade/Proprietary Name:	AperFix® Femoral Implant with Inserter
Common Name:	Bone screw

DEVICE CLASSIFICATION

FDA has classified bone screws as Class II devices (21 CFR 888.3040). The product code for screw, fixation, bone is HWC. These devices are reviewed by the Orthopedic Joint Devices Branch

INTENDED USE

The AperFix® Femoral Implant with Inserter is intended for use in tenodesis procedures with soft tissue grafts, utilizing either arthroscopic or open techniques during Anterior Cruciate Ligament (ACL), Posterior Cruciate Ligament (PCL), Medial Collateral Ligament (MCL), Lateral Collateral Ligament (LCL), and Medial Patellofemoral Ligament (MPFL) reconstruction.

DEVICE DESCRIPTION

The Cayenne Medical AperFix® Femoral Implant with Inserter is a non-absorbable internal fixation device intended to provide tendon to bone fixation in arthroscopic or open procedures such as Anterior Cruciate Ligament (ACL), Posterior Cruciate Ligament (PCL), Medial Collateral Ligament (MCL), Lateral Collateral Ligament (LCL), and Medial Patellofemoral Ligament (MPFL) reconstruction. It includes a body, wedge, two deployable arms, and compression pads. AperFix Femoral Implants are available in diameters of 9, 10 and 11 mm with two different lengths of 29 mm and 35 mm. Each device is intended for single use and is pre-loaded on a sterile inserter.

The AperFix Femoral Implant with Inserter will be supplied sterile. Sterilization is accomplished by means of Co^{60} gamma irradiation at a dose of 25-40 kGy.

Mechanical testing was performed on the AperFix Femoral Implant. It was shown that pull-out strength is significantly higher than that of a predicate device.

EQUIVALENCE TO MARKETED PRODUCT

Cayenne Medical, Inc. demonstrated that, for the purposes of FDA's regulation of medical devices, the AperFix Femoral Implant with Inserter is substantially equivalent in indications and design principles to predicate devices, each of which has been determined by FDA to be substantially equivalent to preamendment devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 4 2009

Cayenne Medical, Inc.
% Ms. Kereshmeh Shahriari
16597 N. 92nd St.
Suite 101
Scottsdale, Arizona 85260

Re: K083612
Trade/Device Name: AperFix® Femoral Implant with Inserter
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: December 3, 2008
Received: December 5, 2008

Dear Ms. Shahriari:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083612

Device Name: AperFix® Femoral Implant with Inserter

Indications for Use:

The AperFix Femoral Implant with Inserter is intended for use in tenodesis procedures with soft tissue grafts, utilizing either arthroscopic or open techniques during Anterior Cruciate Ligament (ACL), Posterior Cruciate Ligament (PCL), Medial Collateral Ligament (MCL), Lateral Collateral Ligament (LCL), and Medial Patellofemoral Ligament (MPFL) reconstruction.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K083612